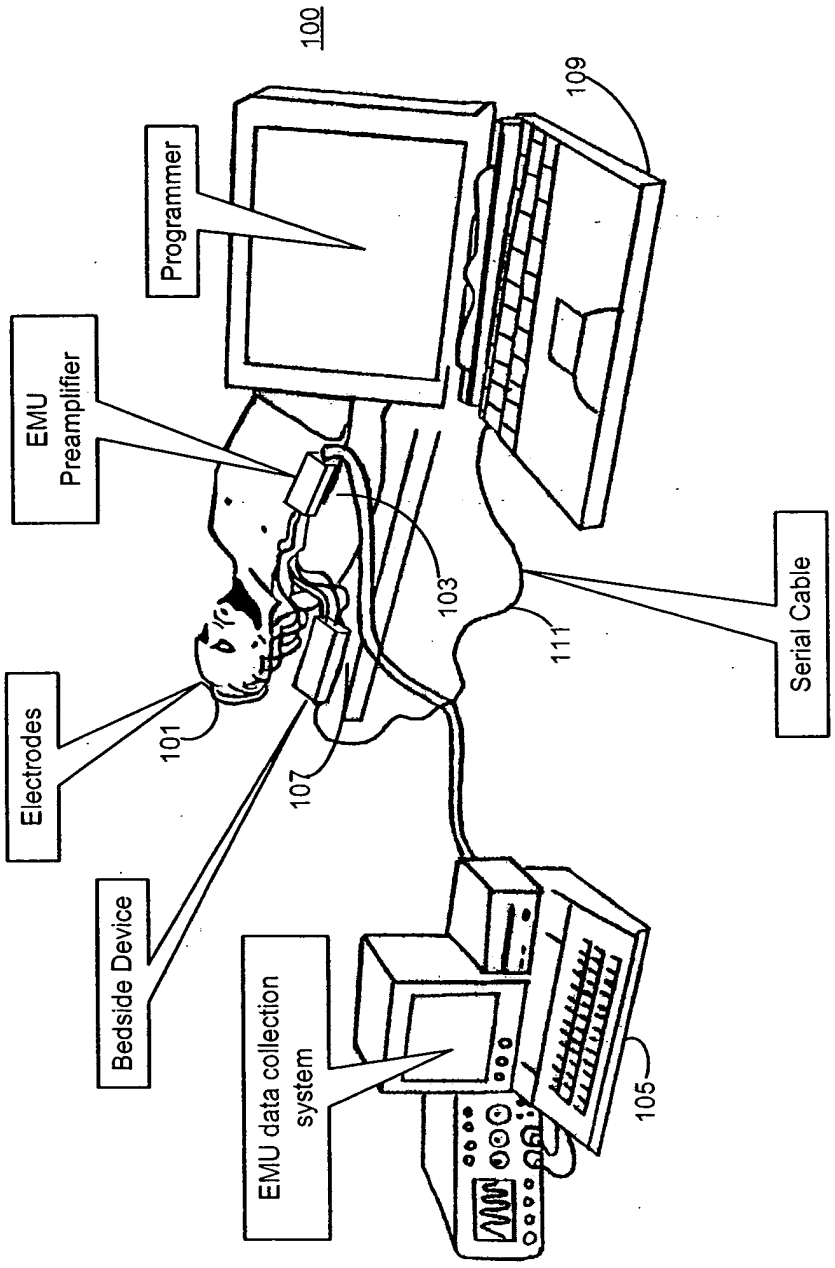


FIG. 1 (CR-ECS configuration)

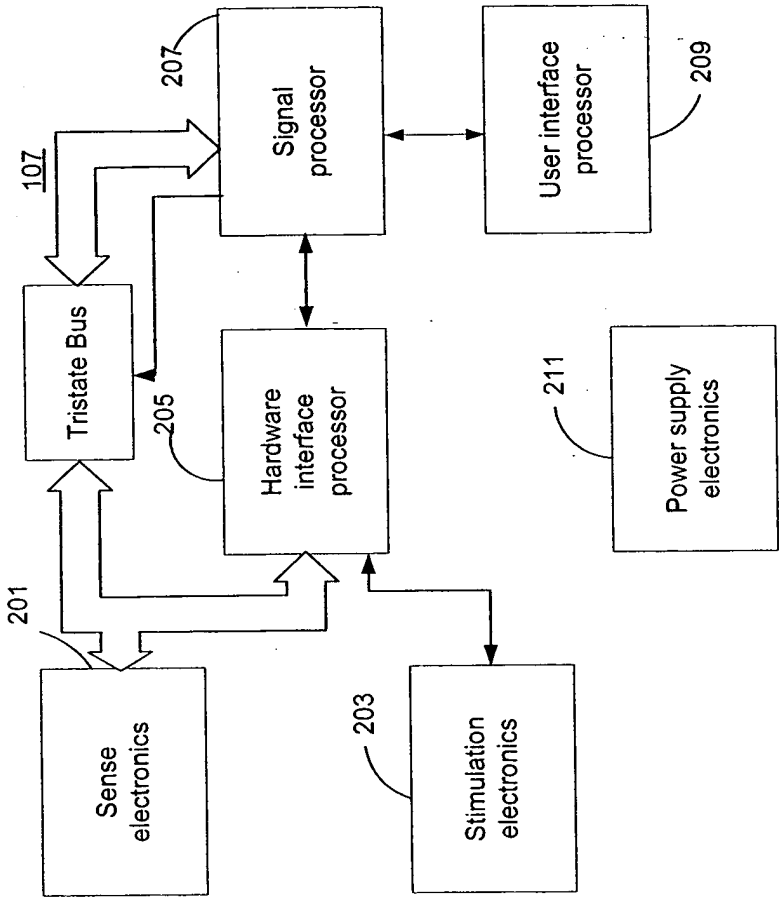
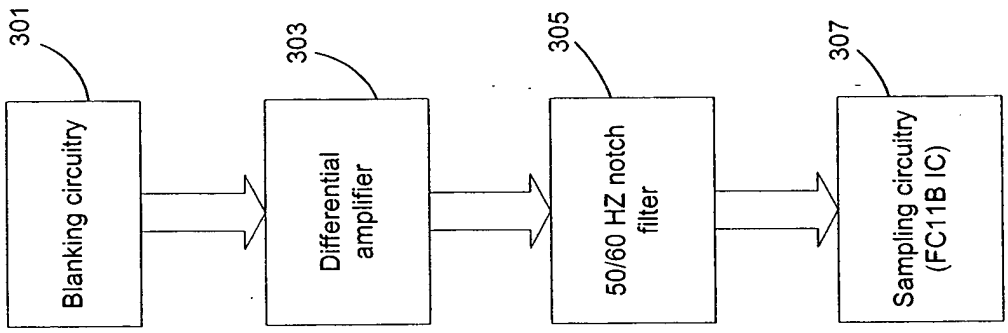


FIG. 2 (Bedside device configuration)

FIG. 3
Sense electronics configuration



201

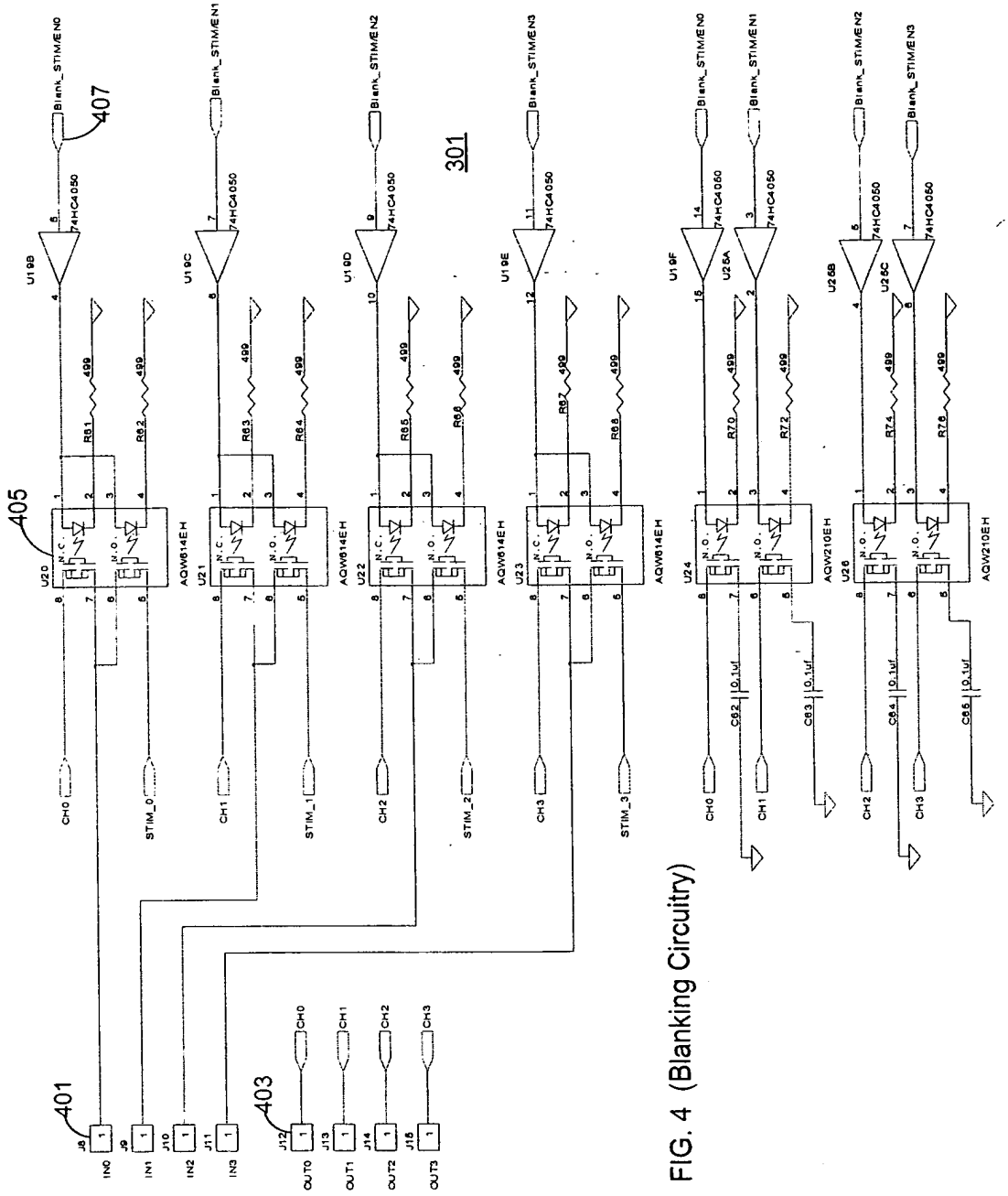


FIG. 4 (Blanking Circuitry)

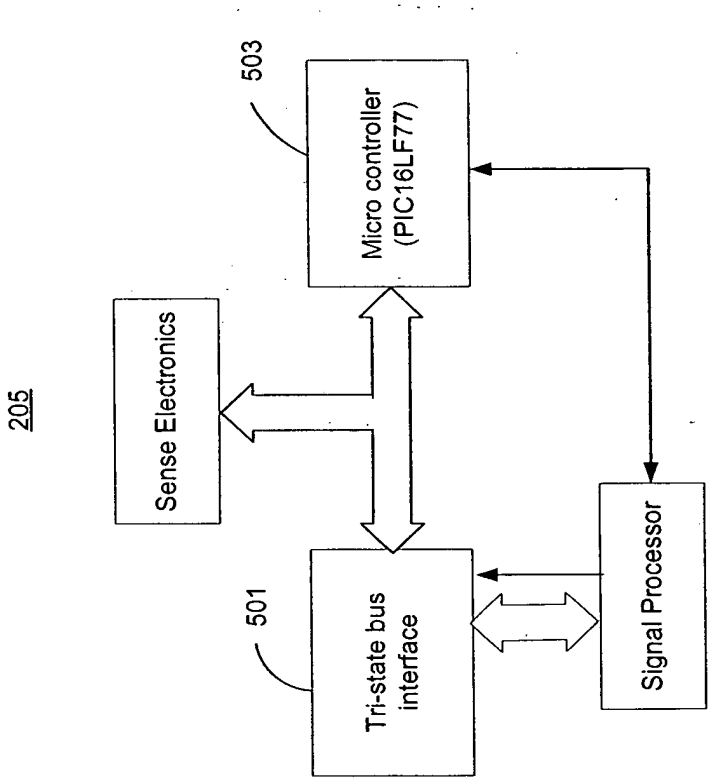


FIG. 5 (Hardware interface processor)

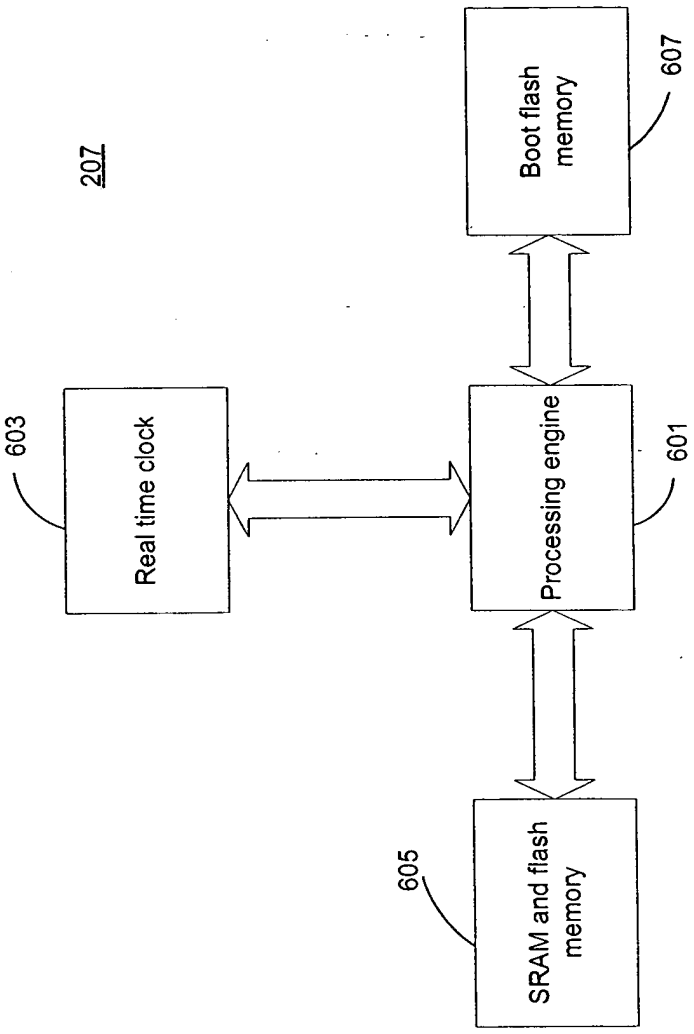


FIG. 6 (Signal processor)

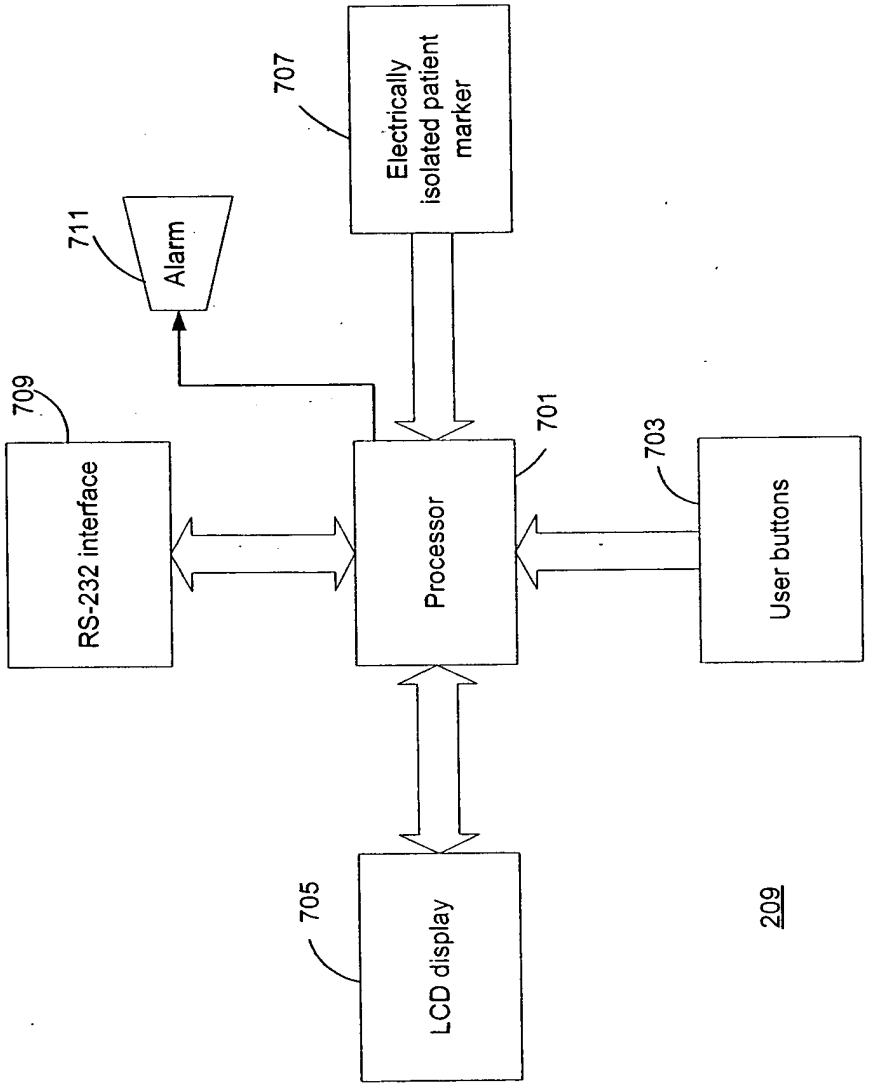


FIG. 7 (User interface processor)

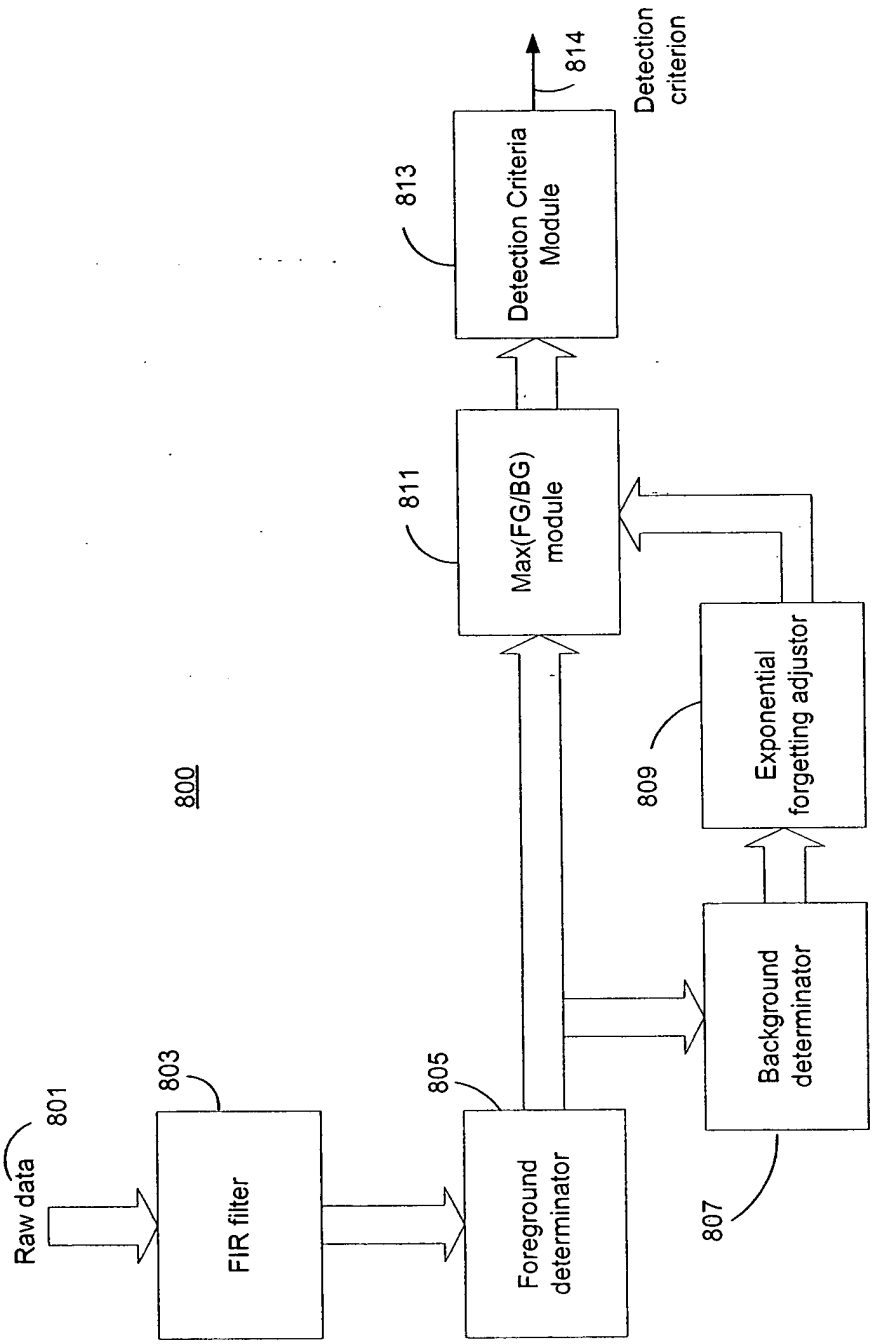


FIG. 8 (Seizure detection algorithm)

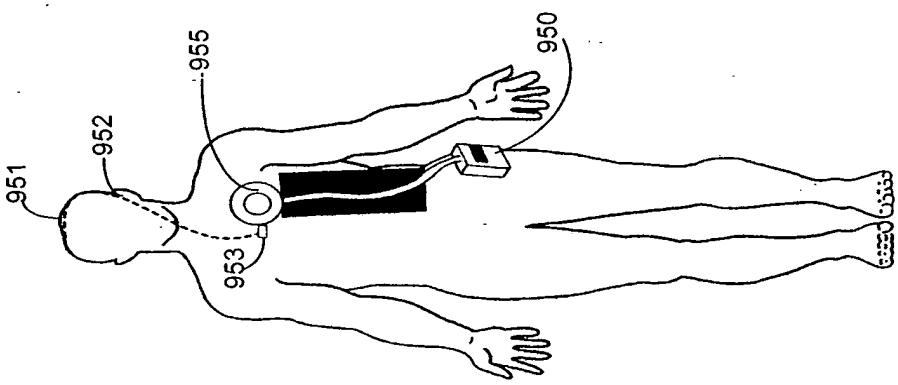


FIG. 9

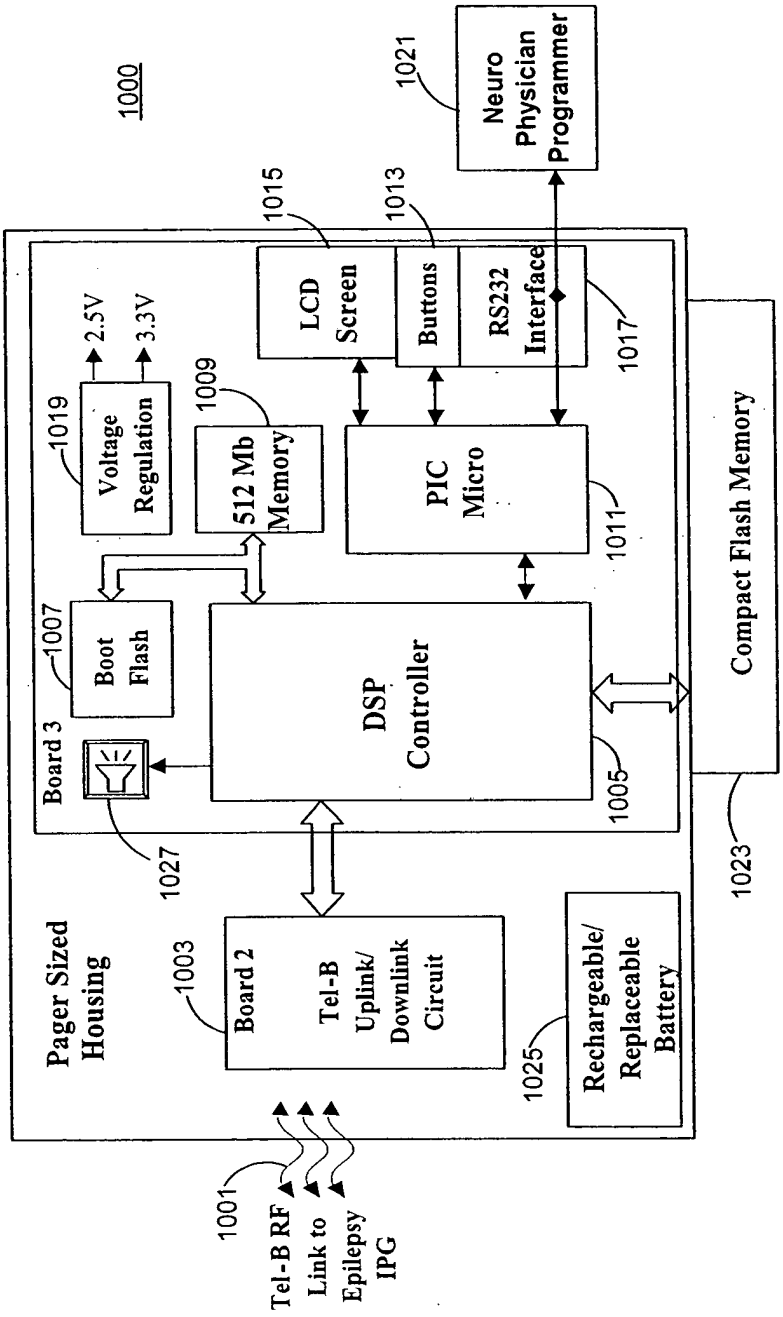


FIG. 10 (Epilepsy external device diagram)

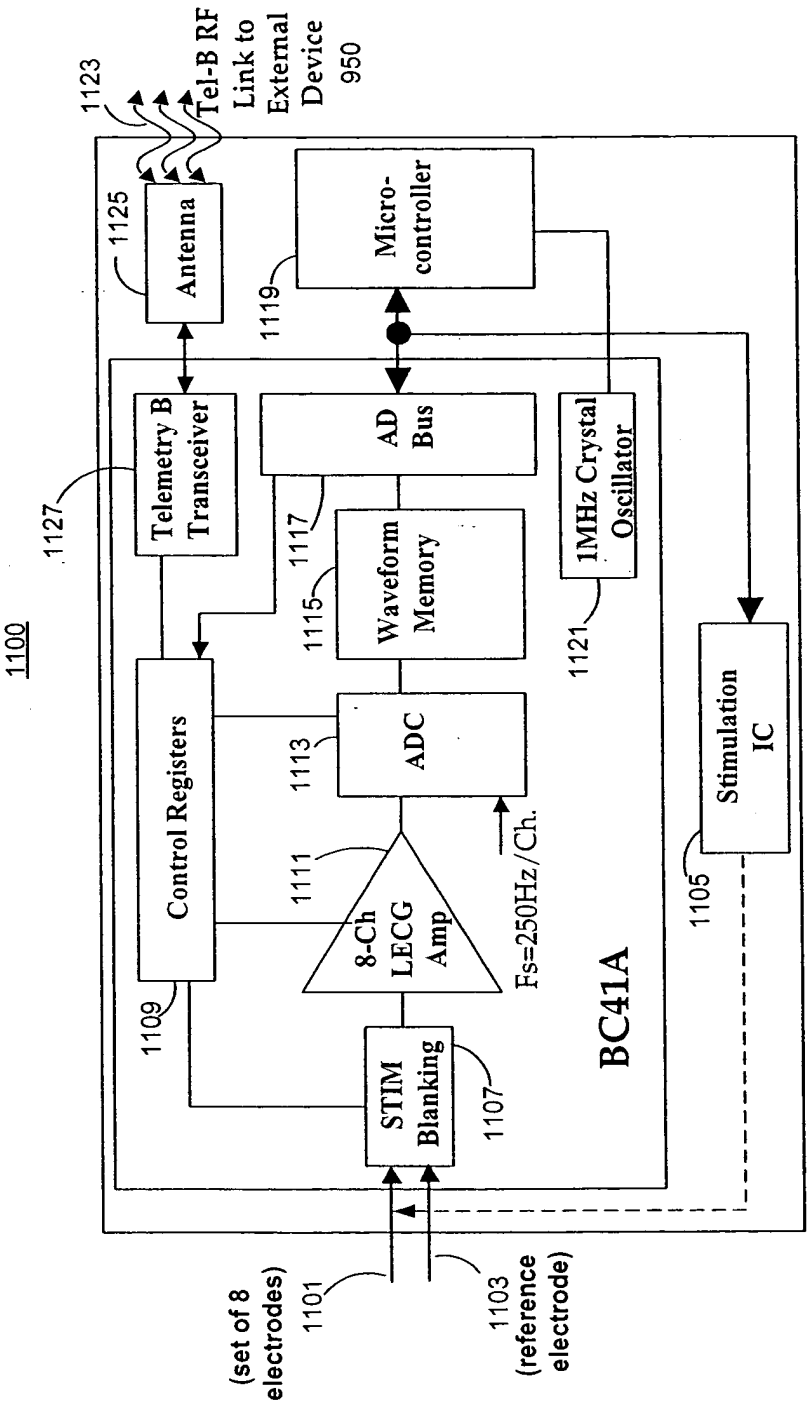


FIG. 11 (Epilepsy implantable device diagram)

FIG. 12

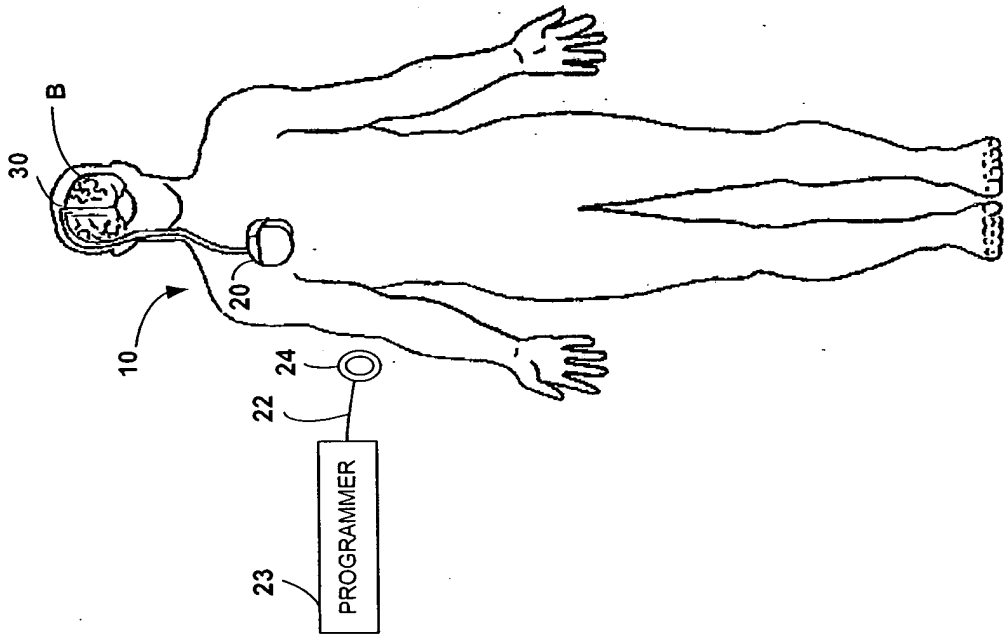
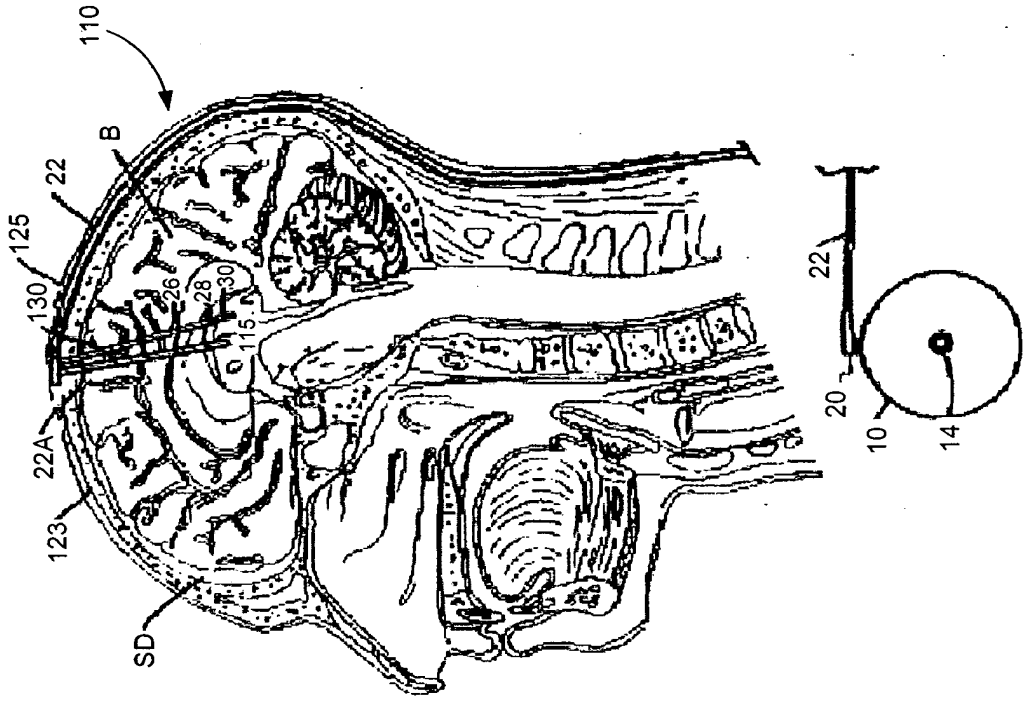


FIG. 13



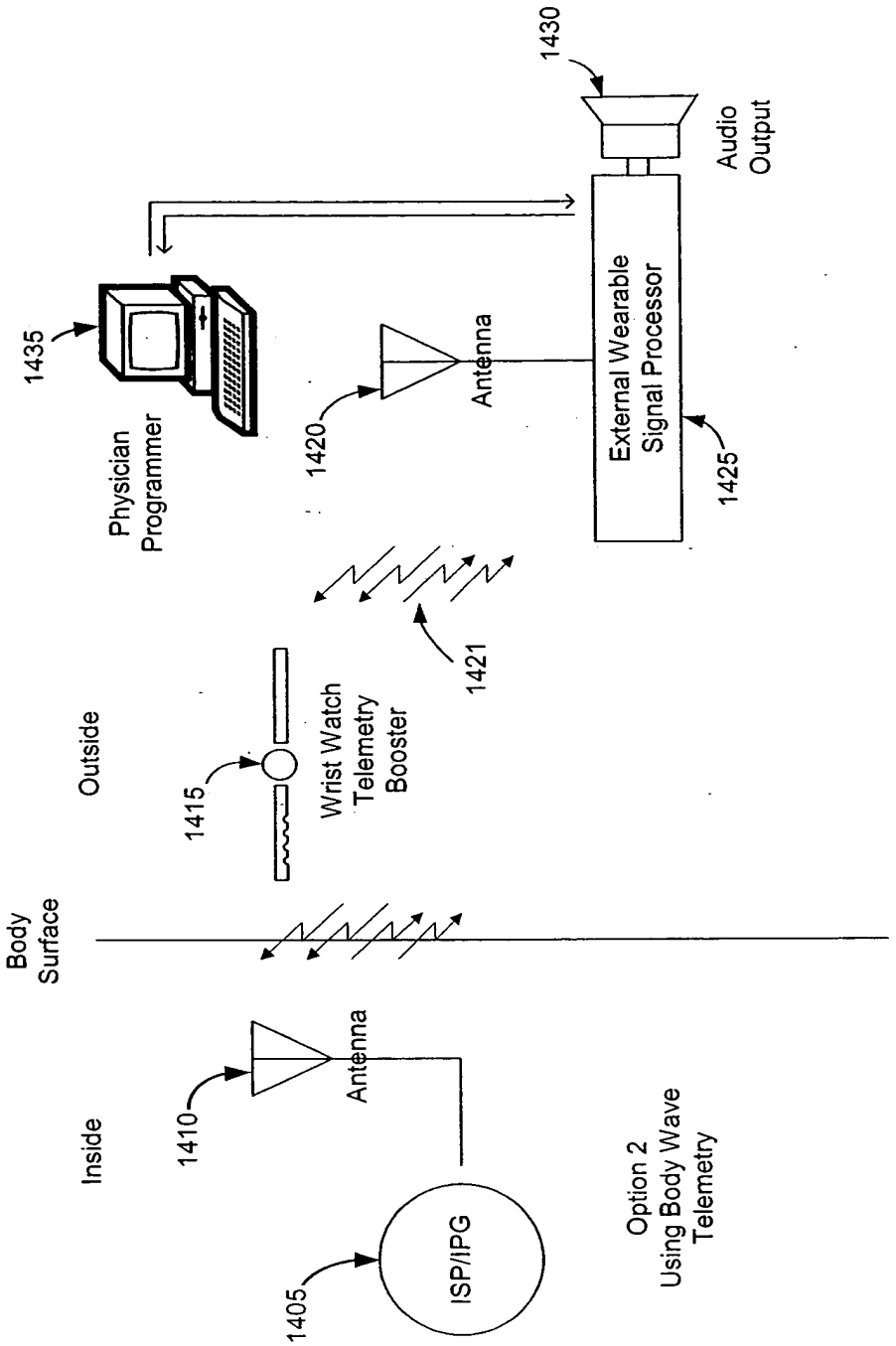
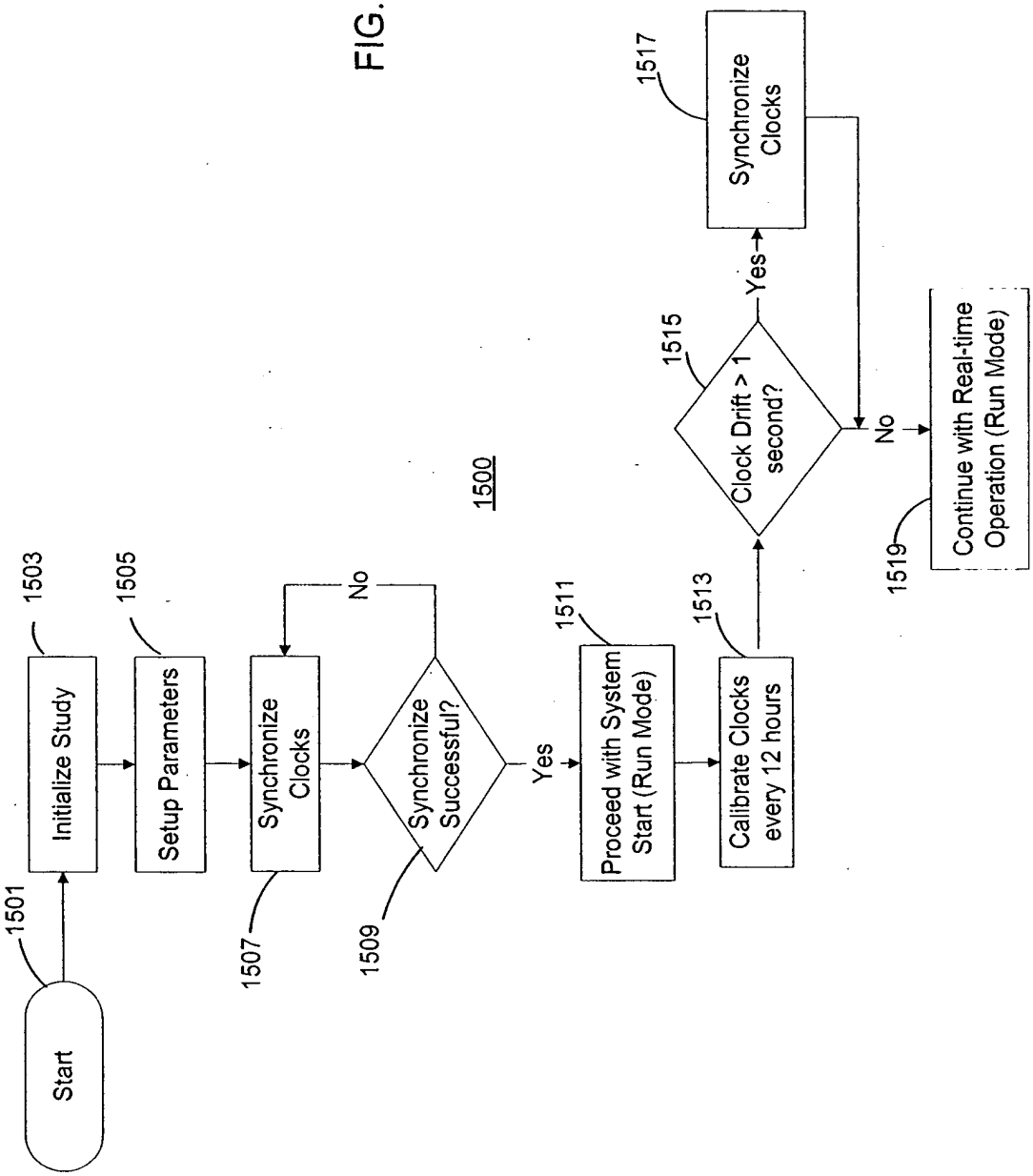

1430
Audio Output
External Wearable Signal Processor
1425
1435
Physician Programmer
1420
Antenna
1421
Outside
1415
Wrist Watch Telemetry Booster
Body Surface
Inside
1410
Antenna
1405
ISP/IPG
Option 2
Using Body Wave Telemetry

FIG. 14

FIG. 15


1500
Start
1501
Initialize Study
1503
Setup Parameters
1505
Synchronize Clocks
1507
Synchronize Successful?
1509
No
Yes
Proceed with System Start (Run Mode)
1511
Calibrate Clocks every 12 hours
1513
Clock Drift > 1 second?
1515
Yes
Synchronize Clocks
1517
No
Continue with Real-time Operation (Run Mode)
1519

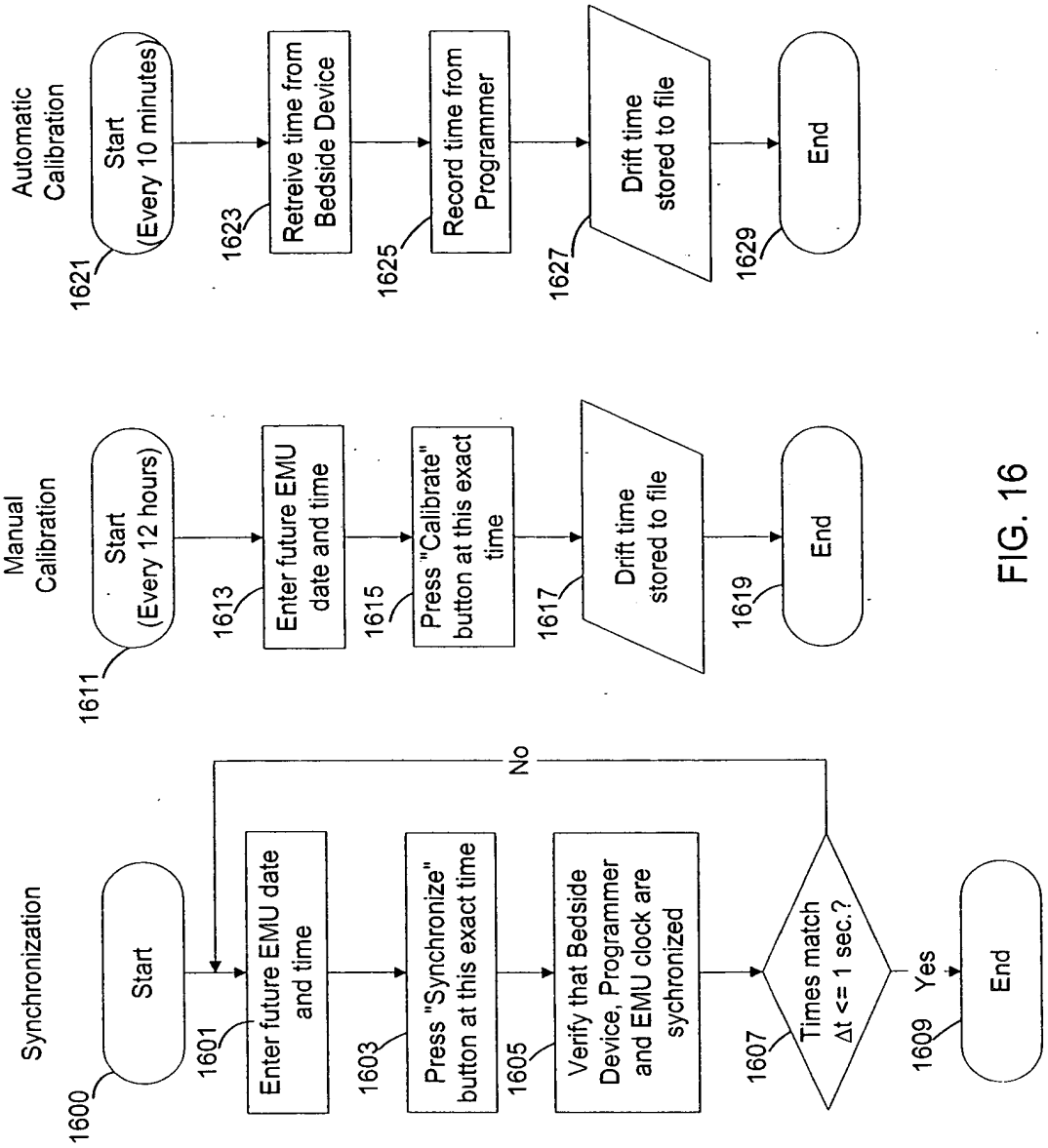

Synchronization
Start
1600
Enter future EMU date and time
1601
Press "Synchronize" button at this exact time
1603
Verify that Bedside Device, Programmer and EMU clock are sychronized
1605
Times match Δt <= 1 sec.?
1607
No
Yes
1609
End
Manual Calibration
Start (Every 12 hours)
1611
Enter future EMU date and time
1613
Press "Calibrate" button at this exact time
1615
Drift time stored to file
1617
End
1619
Automatic Calibration
Start (Every 10 minutes)
1621
Retreive time from Bedside Device
1623
Record time from Programmer
1625
Drift time stored to file
1627
End
1629

FIG. 16

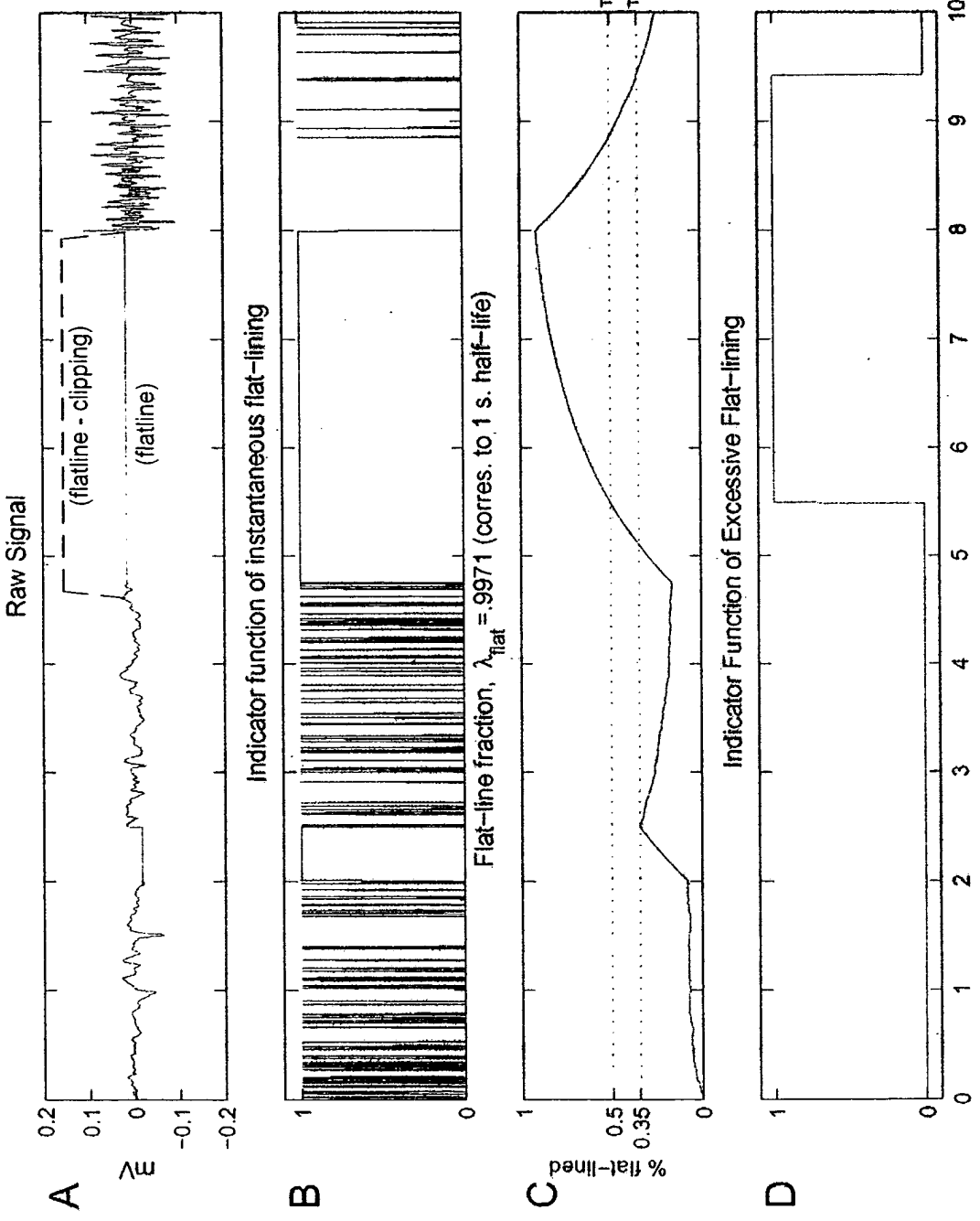

A
Raw Signal
(flatline - clipping)
(flatline)
mV
0.2
0.1
0
-0.1
-0.2
B
Indicator function of instantaneous flat-lining
1
0
Flat-line fraction, λ_{flat} = .9971 (corres. to 1 s. half-life)
C
% flat-lined
1
0.5
0.35
0
D
Indicator Function of Excessive Flat-lining
1
0
0 1 2 3 4 5 6 7 8 9 10

FIG. 17

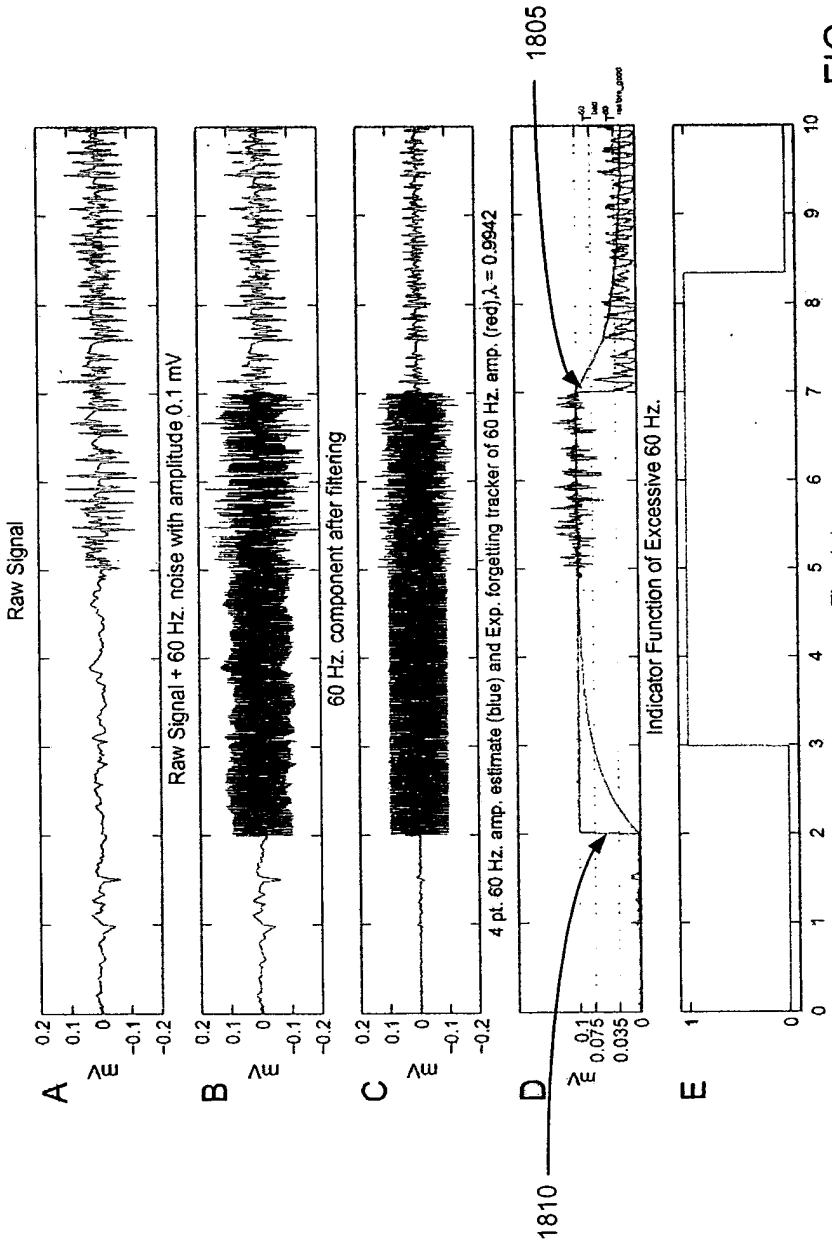

Raw Signal
A
Raw Signal + 60 Hz. noise with amplitude 0.1 mV
B
60 Hz. component after filtering
C
4 pt. 60 Hz. amp. estimate (blue) and Exp. forgetting tracker of 60 Hz. amp. (red),λ = 0.9942
D
Indicator Function of Excessive 60 Hz.
E
mV
Time (s.)
1805
1810

FIG. 18

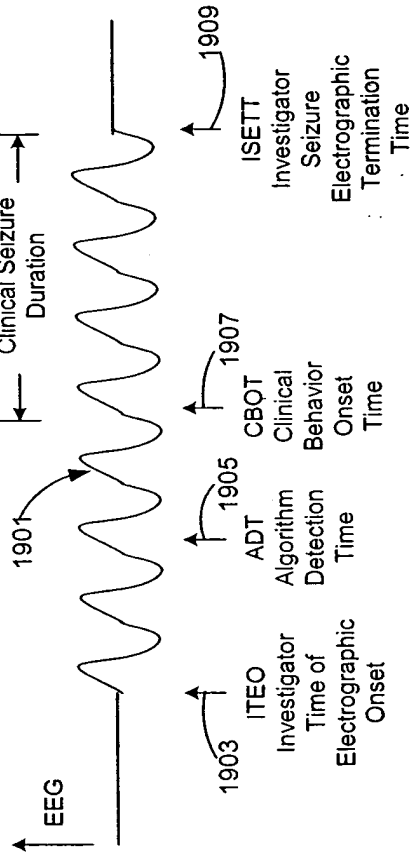

EEG
1901
1903
ITEO
Investigator
Time of
Electrographic
Onset
1905
ADT
Algorithm
Detection
Time
1907
CBOT
Clinical
Behavior
Onset
Time
1909
ISETT
Investigator
Seizure
Electrographic
Termination
Time
1911
Clinical Seizure
Duration

FIG. 19

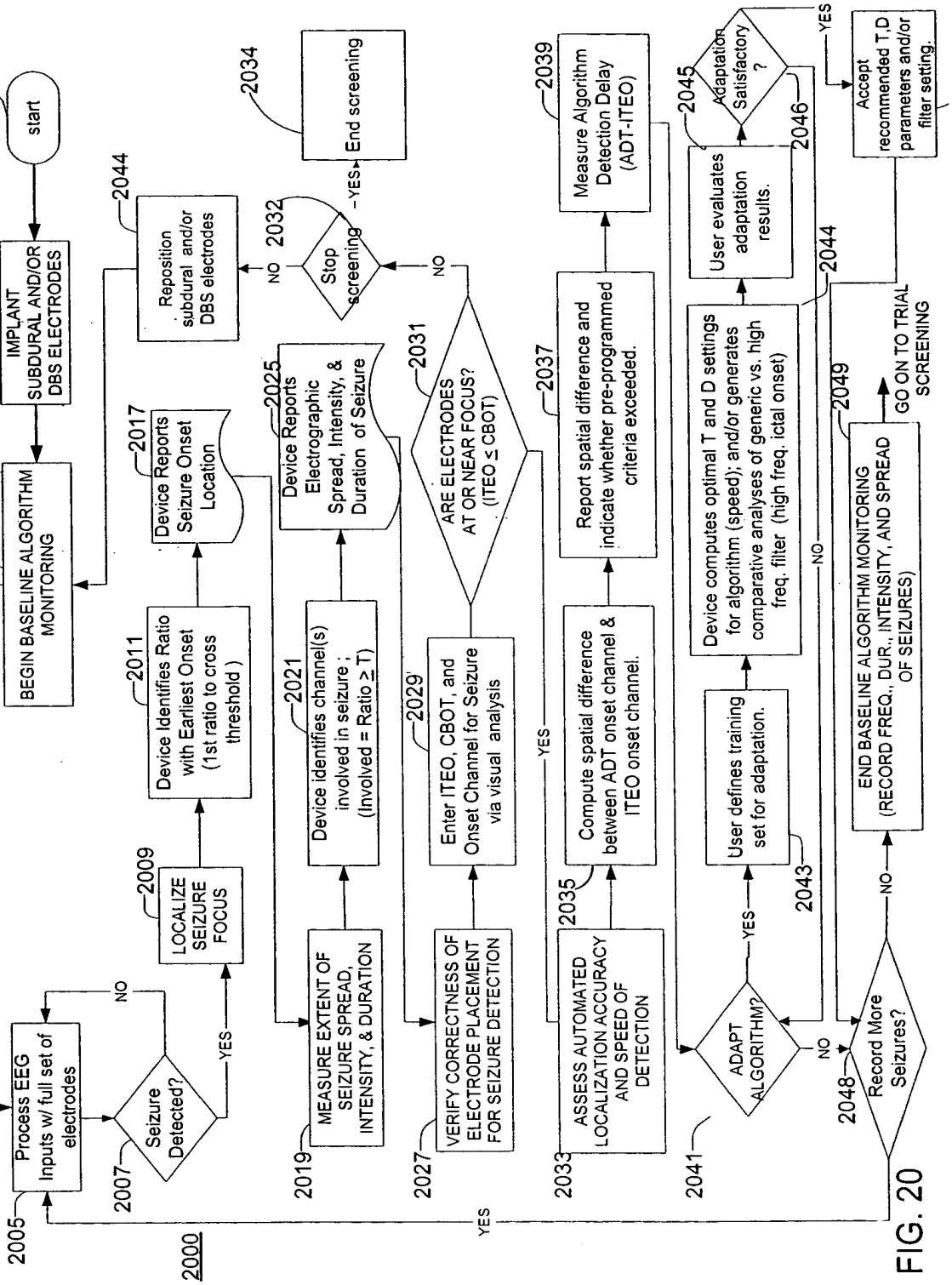

2001
start
2002
IMPLANT SUBDURAL AND/OR DBS ELECTRODES
2003
BEGIN BASELINE ALGORITHM MONITORING
2005
Process EEG Inputs w/ full set of electrodes
2007
Seizure Detected?
NO
YES
2009
LOCALIZE SEIZURE FOCUS
2011
Device Identifies Ratio with Earliest Onset (1st ratio to cross threshold)
2017
Device Reports Seizure Onset Location
2019
MEASURE EXTENT OF SEIZURE SPREAD, INTENSITY, & DURATION
2021
Device identifies channel(s) involved in seizure ; (Involved = Ratio ≥ T)
2025
Device Reports Electrographic Spread, Intensity, & Duration of Seizure
2027
VERIFY CORRECTNESS OF ELECTRODE PLACEMENT FOR SEIZURE DETECTION
2029
Enter ITEO, CBOT, and Onset Channel for Seizure via visual analysis
2031
ARE ELECTRODES AT OR NEAR FOCUS? (ITEO ≤ CBOT)
2032
Stop screening
2033
ASSESS AUTOMATED LOCALIZATION ACCURACY AND SPEED OF DETECTION
2034
End screening
2035
Compute spatial difference between ADT onset channel & ITEO onset channel.
2037
Report spatial difference and indicate whether pre-programmed criteria exceeded.
2039
Measure Algorithm Detection Delay (ADT-ITEO)
2041
ADAPT ALGORITHM?
2043
User defines training set for adaptation.
2044
Reposition subdural and/or DBS electrodes
2045
Device computes optimal T and D settings for algorithm (speed); and/or generates comparative analyses of generic vs. high freq. filter (high freq. ictal onset)
2046
User evaluates adaptation results.
Adaptation Satisfactory ?
2048
Record More Seizures?
2049
END BASELINE ALGORITHM MONITORING (RECORD FREQ., DUR., INTENSITY, AND SPREAD OF SEIZURES)
Accept recommended T,D parameters and/or filter setting.
GO ON TO TRIAL SCREENING
YES
NO
2000

FIG. 20

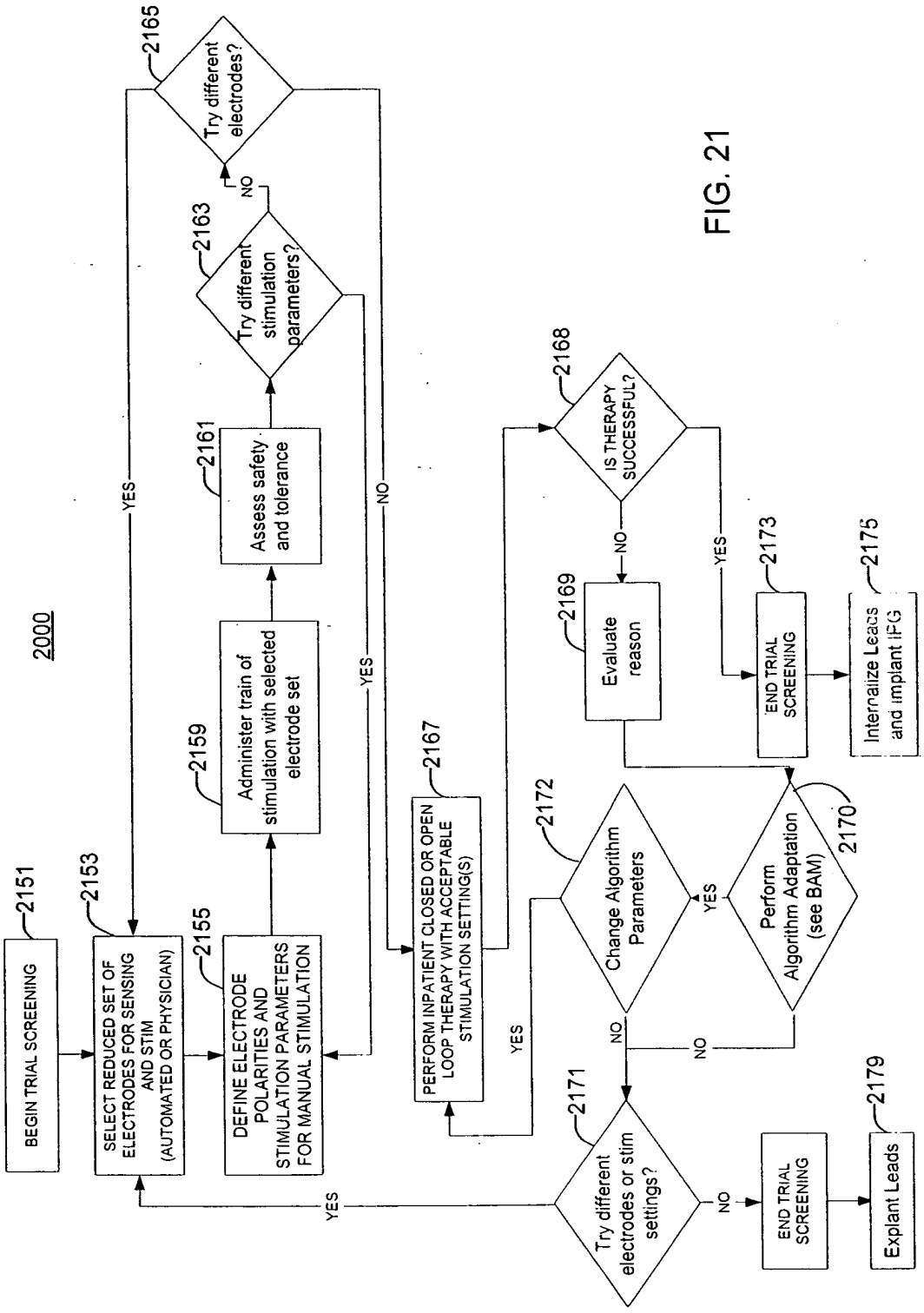

2000
BEGIN TRIAL SCREENING
2151
SELECT REDUCED SET OF ELECTRODES FOR SENSING AND STIM (AUTOMATED OR PHYSICIAN)
2153
DEFINE ELECTRODE POLARITIES AND STIMULATION PARAMETERS FOR MANUAL STIMULATION
2155
Administer train of stimulation with selected electrode set
2159
Assess safety and tolerance
2161
Try different stimulation parameters?
2163
Try different electrodes?
2165
PERFORM INPATIENT CLOSED OR OPEN LOOP THERAPY WITH ACCEPTABLE STIMULATION SETTING(S)
2167
IS THERAPY SUCCESSFUL?
2168
Evaluate reason
2169
Change Algorithm Parameters
2172
Perform Algorithm Adaptation (see BAM)
2170
END TRIAL SCREENING
2173
Internalize Leads and implant IPG
2175
Try different electrodes or stim settings?
2171
END TRIAL SCREENING
Explant Leads
2179
YES
NO

FIG. 21

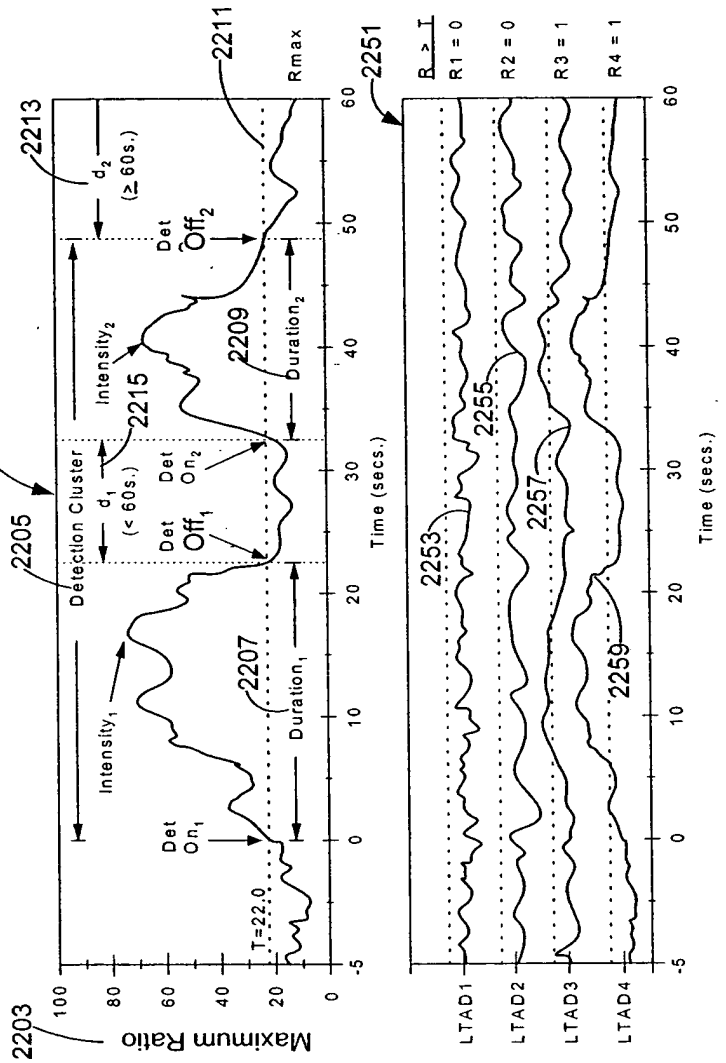


FIG. 22 (Clustering)

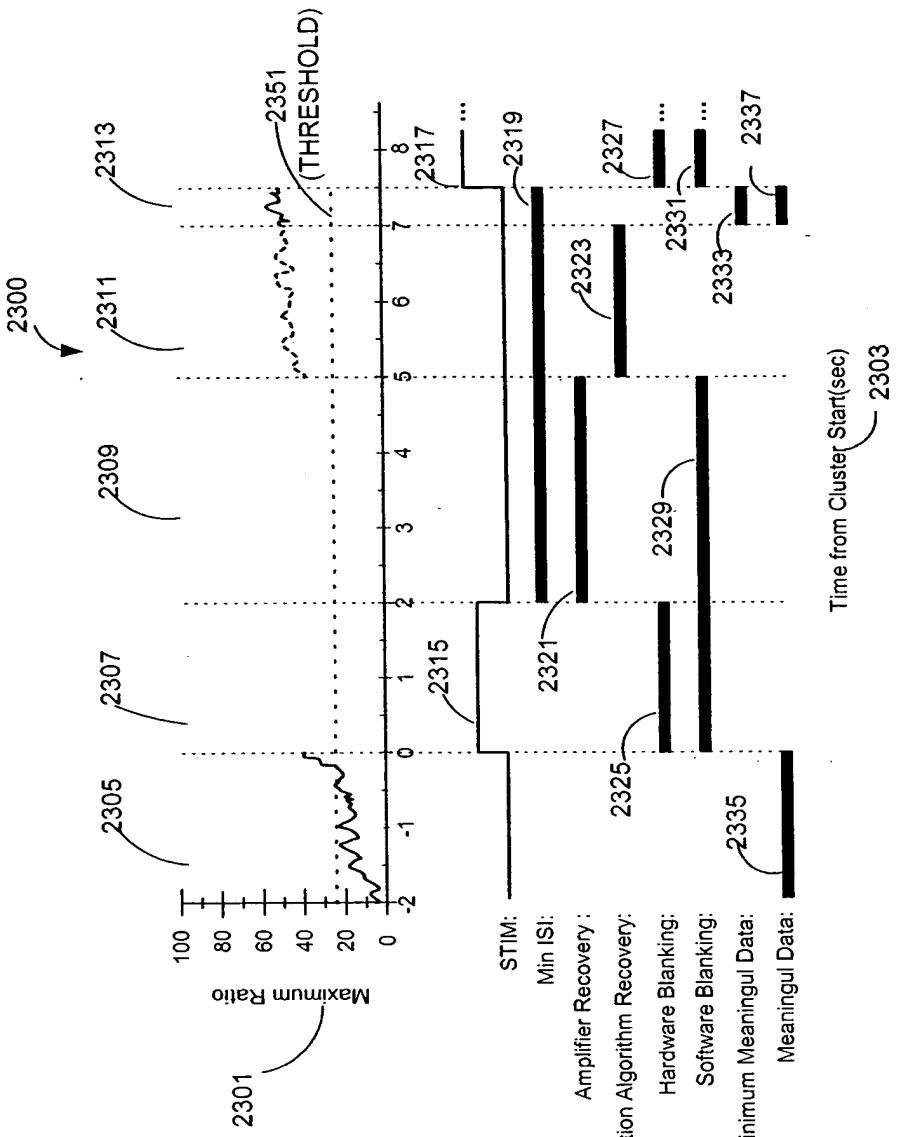
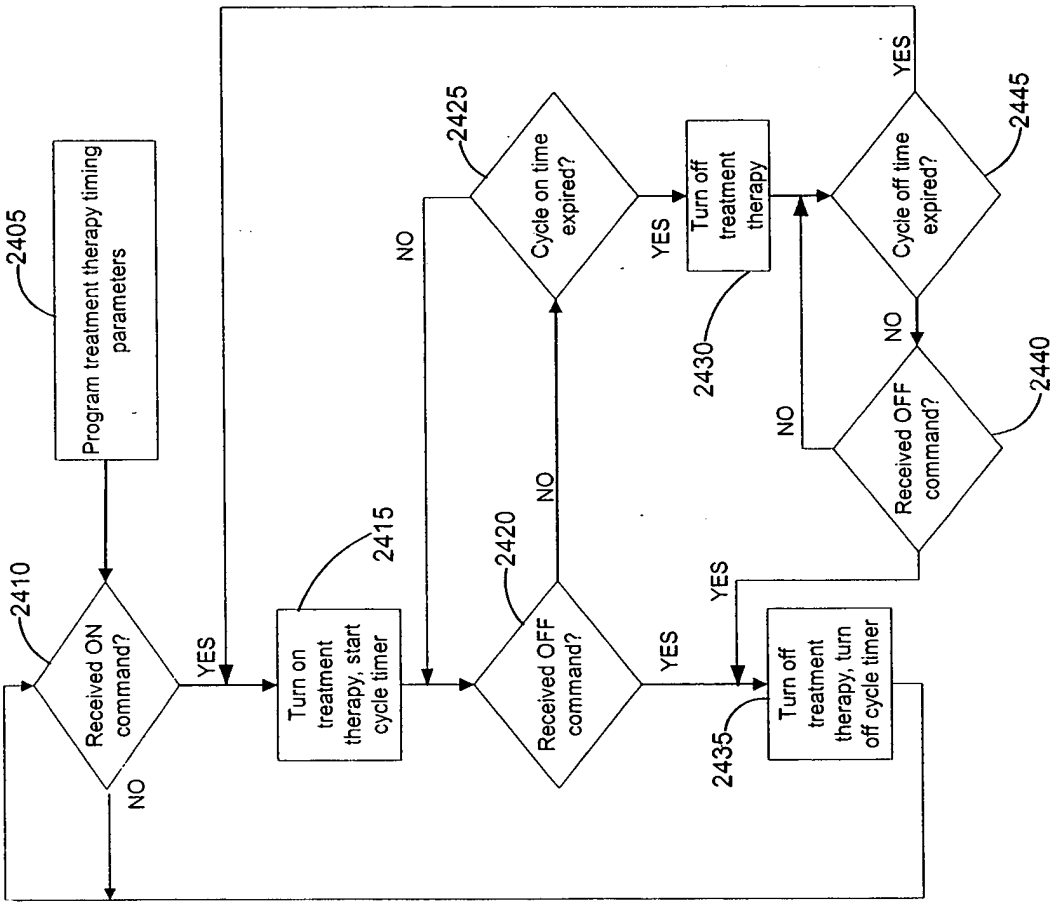

2300
2301
2303
2305
2307
2309
2311
2313
2315
2317
2319
2321
2323
2325
2327
2329
2331
2333
2335
2337
2351
(THRESHOLD)
Maximum Ratio
100
80
60
40
20
0
-2
-1
0
1
2
3
4
5
6
7
8
STIM:
Min ISI:
Amplifier Recovery:
Detection Algorithm Recovery:
Hardware Blanking:
Software Blanking:
Minimum Meaningul Data:
Meaningul Data:
Time from Cluster Start(sec)

FIG. 23

FIG. 24


2405
Program treatment therapy timing parameters
2410
Received ON command?
YES
NO
2415
Turn on treatment therapy, start cycle timer
2420
Received OFF command?
NO
YES
2425
Cycle on time expired?
NO
YES
2430
Turn off treatment therapy
2435
Turn off treatment therapy, turn off cycle timer
2440
Received OFF command?
NO
YES
2445
Cycle off time expired?
NO
YES

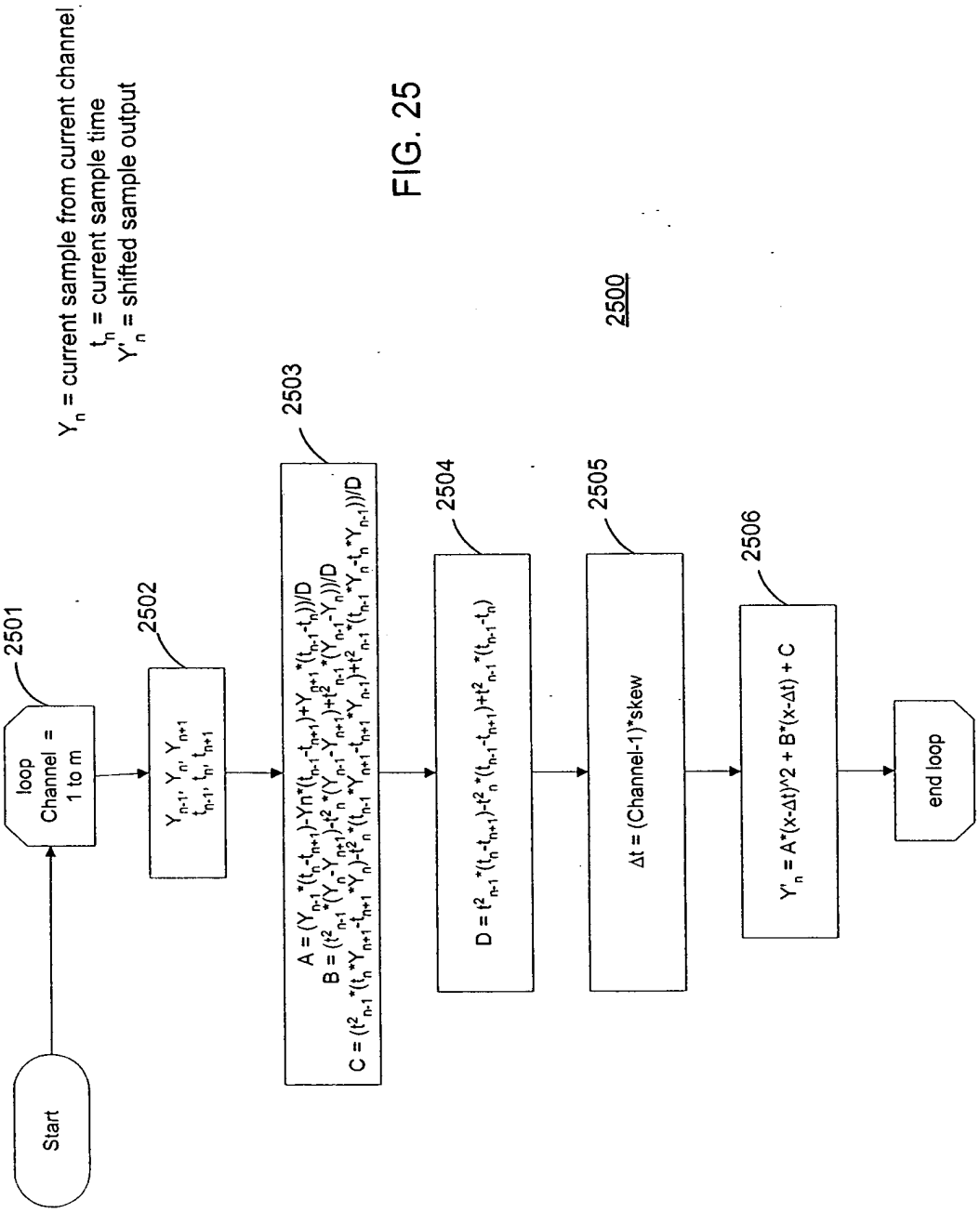
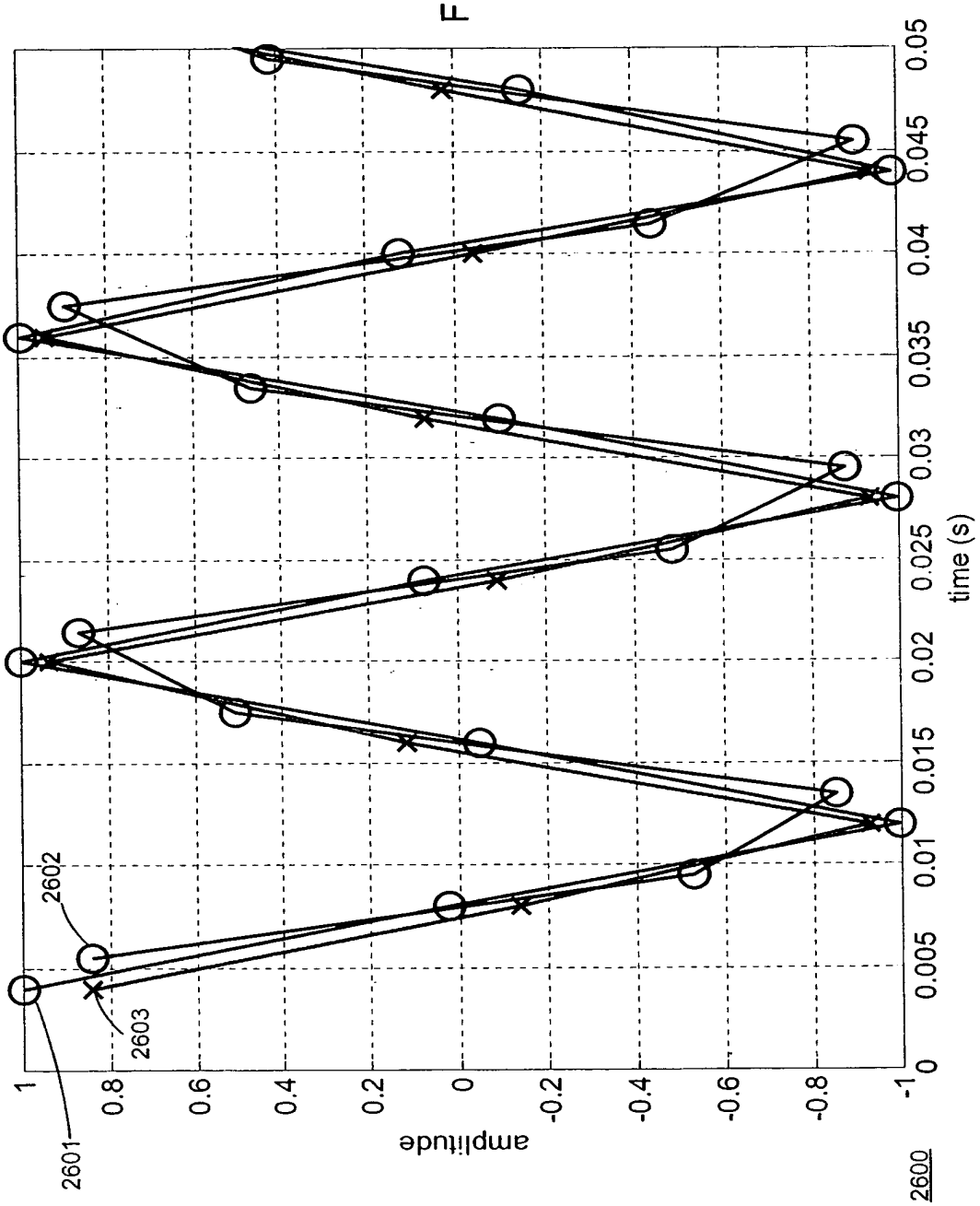

Y_n = current sample from current channel
t_n = current sample time
Y'_n = shifted sample output
2500
Start
2501
loop
Channel = 1 to m
2502
Y_{n-1}, Y_n, Y_{n+1}
t_{n-1}, t_n, t_{n+1}
2503
$A = (Y_{n-1}*(t_n-t_{n+1})-Yn*(t_{n-1}-t_{n+1})+Y_{n+1}*(t_{n-1}-t_n))/D$
$B = (t^2_{n-1}*(Y_n-Y_{n+1})-t^2_n*(Y_{n-1}-Y_{n+1})+t^2_{n+1}*(Y_{n-1}-Y_n))/D$
$C = (t^2_{n-1}*(t_n*Y_{n+1}-t_{n+1}*Y_n)-t^2_n*(t_{n-1}*Y_{n+1}-t_{n+1}*Y_{n-1})+t^2_{n-1}*(t_{n-1}*Y_n-t_n*Y_{n-1}))/D$
2504
$D = t^2_{n-1}*(t_n-t_{n+1})-t^2_n*(t_{n-1}-t_{n+1})+t^2_{n-1}*(t_{n-1}-t_n)$
2505
Δt = (Channel-1)*skew
2506
$Y'_n = A*(x-\Delta t)^2 + B*(x-\Delta t) + C$
end loop

FIG. 25

FIG. 26


amplitude
1
0.8
0.6
0.4
0.2
0
-0.2
-0.4
-0.6
-0.8
-1
time (s)
0
0.005
0.01
0.015
0.02
0.025
0.03
0.035
0.04
0.045
0.05
2600
2601
2602
2603

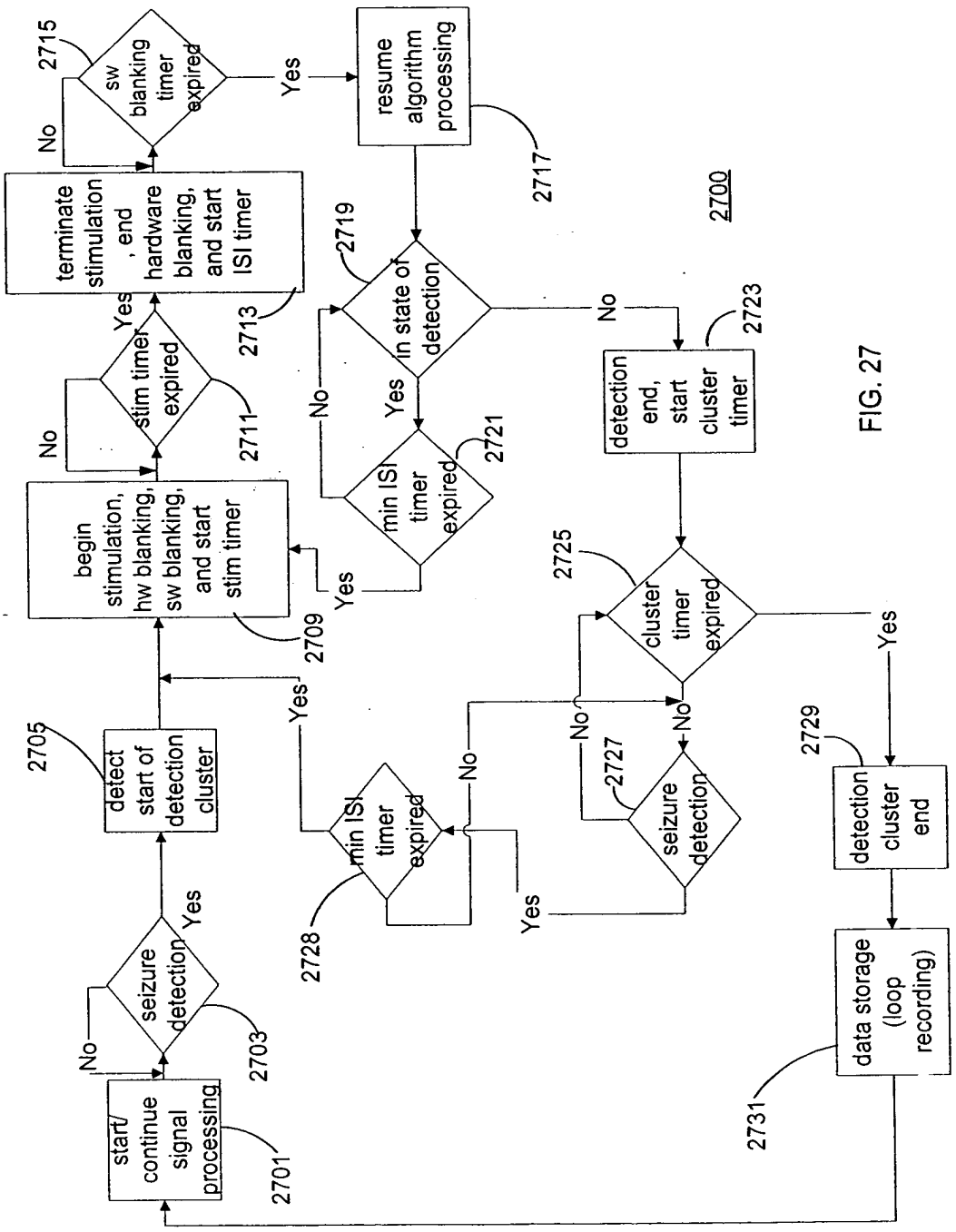

start/ continue signal processing
2701
seizure detection
2703
Yes
No
detect start of detection cluster
2705
begin stimulation, hw blanking, sw blanking, and start stim timer
2709
stim timer expired
2711
No
Yes
terminate stimulation , end hardware blanking, and start ISI timer
2713
sw blanking timer expired
2715
No
Yes
resume algorithm processing
2717
in state of detection
2719
No
Yes
min ISI timer expired
2721
No
Yes
detection end, start cluster timer
2723
seizure detection
2727
No
Yes
min ISI timer expired
2728
No
Yes
cluster timer expired
2725
No
Yes
detection cluster end
2729
data storage (loop recording)
2731
2700

FIG. 27

FIG. 28

Graph of $P(x; 0, 8, \{\})$:

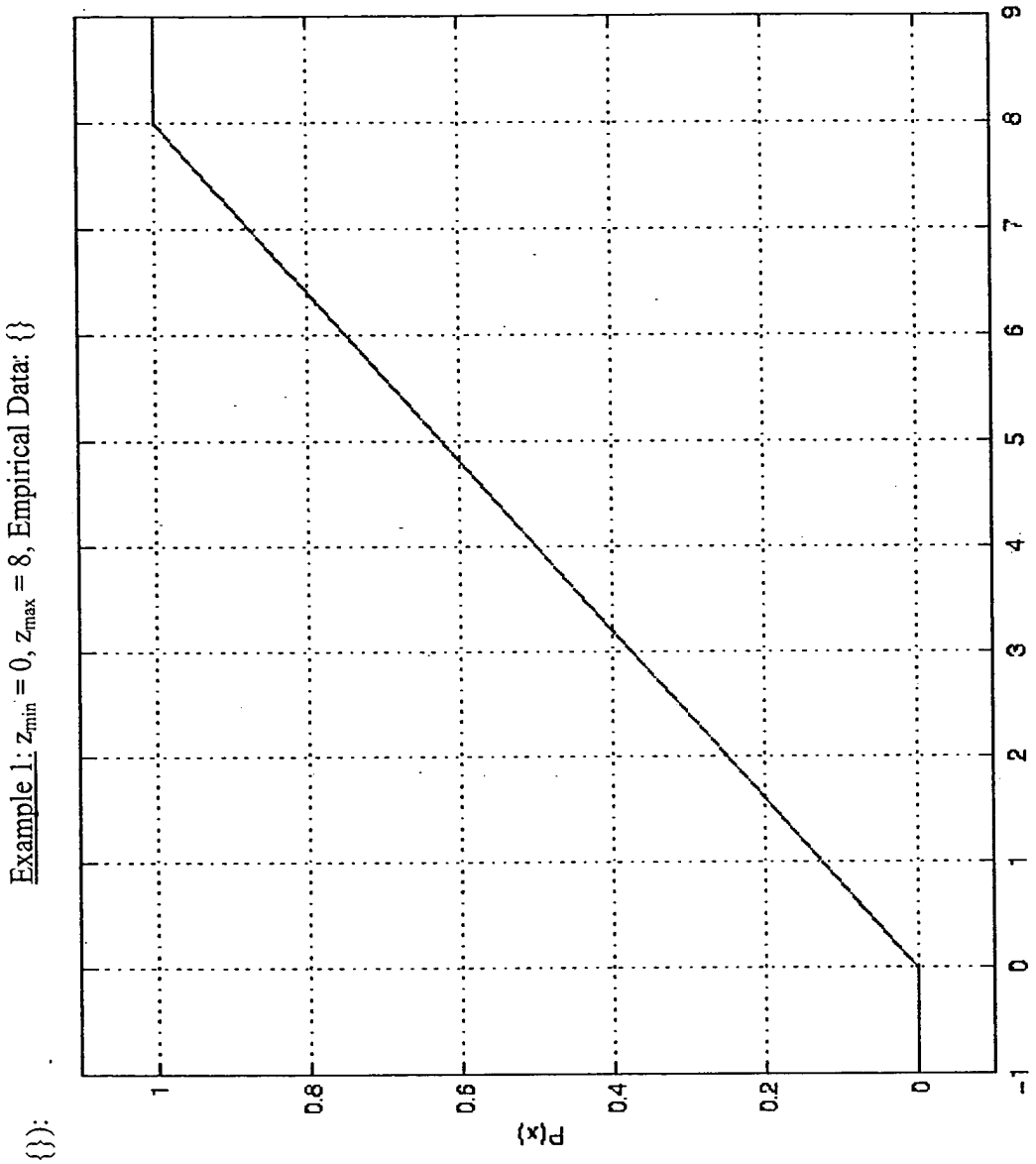
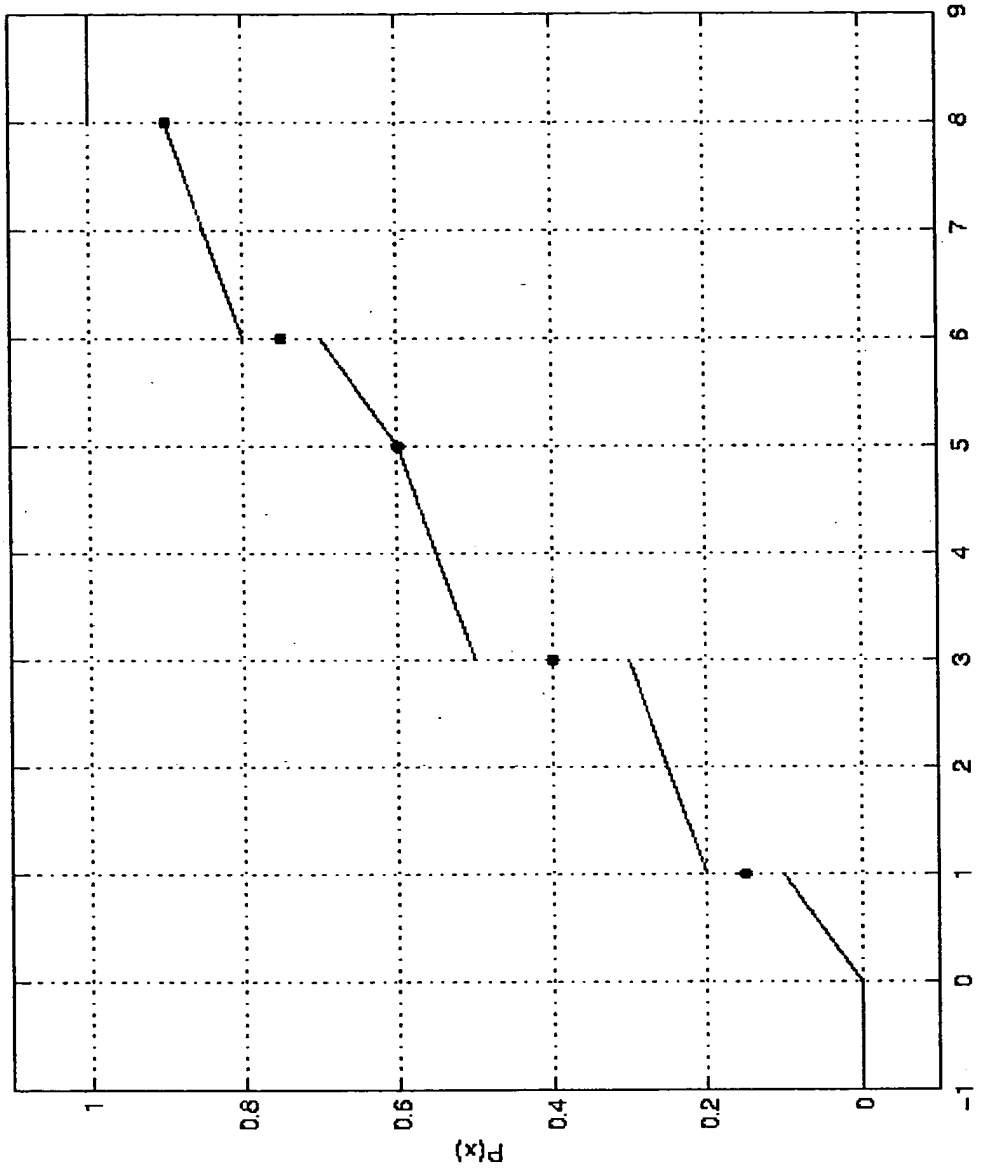


FIG. 29

Graph of $P(x; 0, 8, \{1,1,3,3,3,5,6,6,8\})$: Example 2: $z_{min} = 0$, $z_{max} = 8$, Empirical Data: {1,1,3,3,3,5,6,6,8}



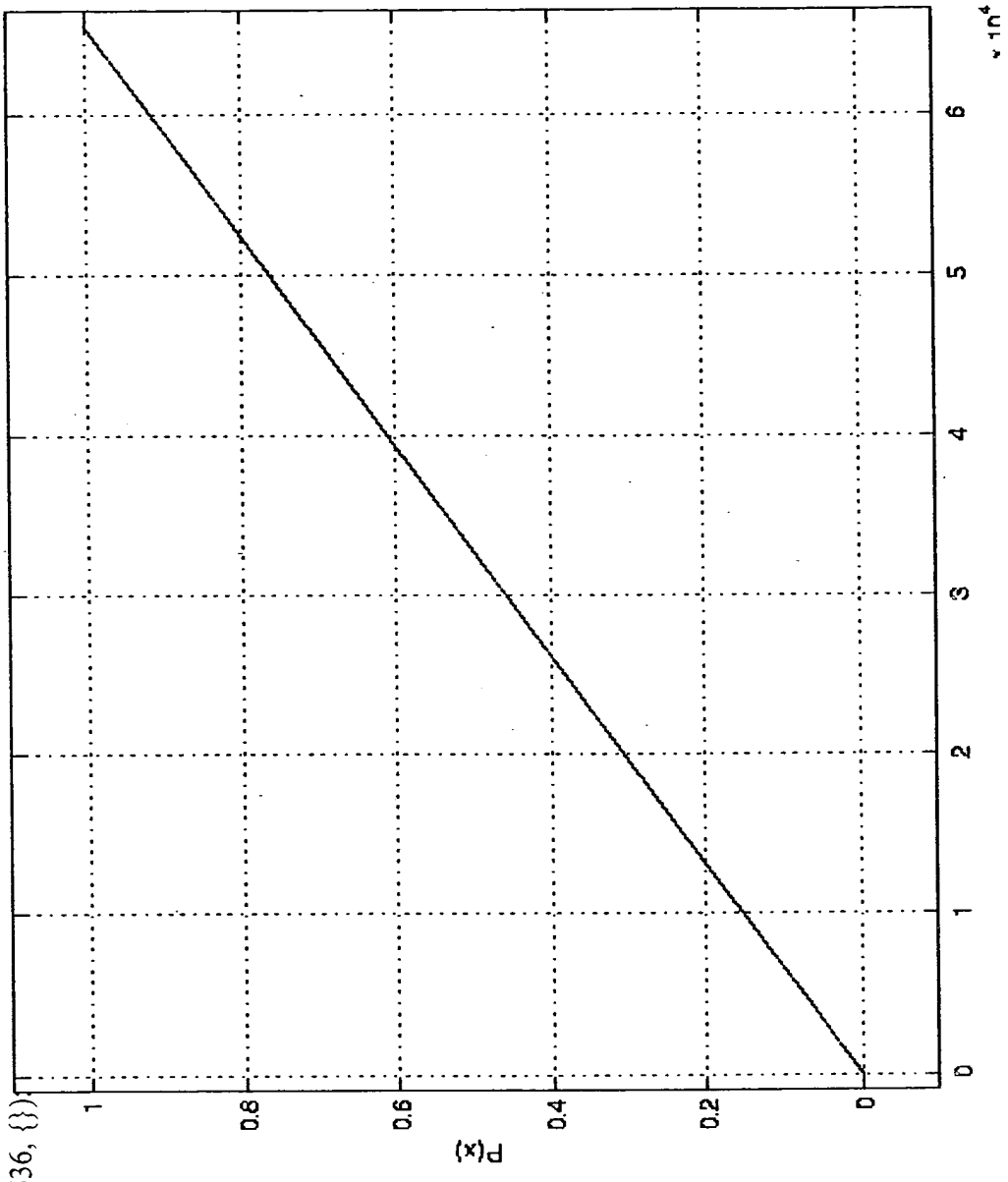
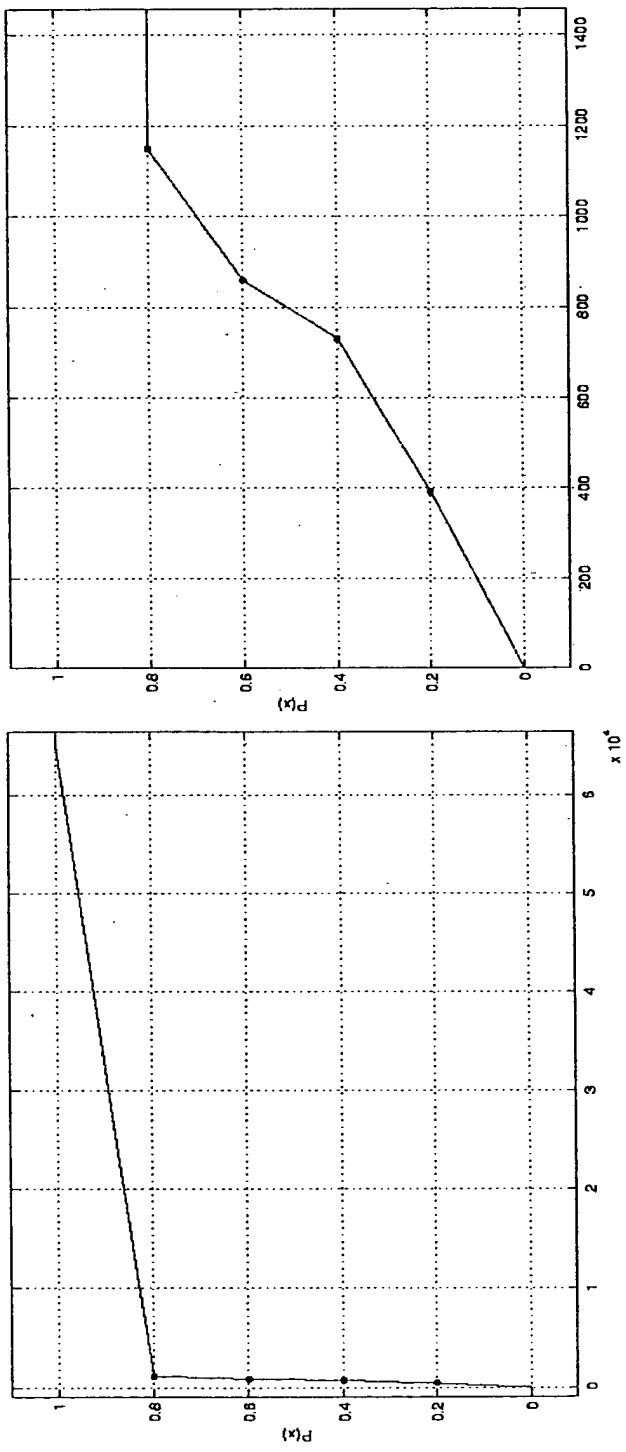

Example 3: $z_{min} = 0$, $z_{max} = 65536$, Empirical Data: {}
Graph of $P(x; 0, 65536, \{\})$
P(x)
1
0.8
0.6
0.4
0.2
0
0
1
2
3
4
5
6
x 10^4

FIG. 30

FIG. 31

Graph of $P(x; 0, 65536, \{\text{round}([35.2, 41.3, 18.9, 55.1]*(250/12))\}) = P(x; 0, 65536, \{394, 733, 860, 1148\})$



Example 4: $z_{min} = 0$, $z_{max} = 65536$, Empirical Data: {923, 1058}

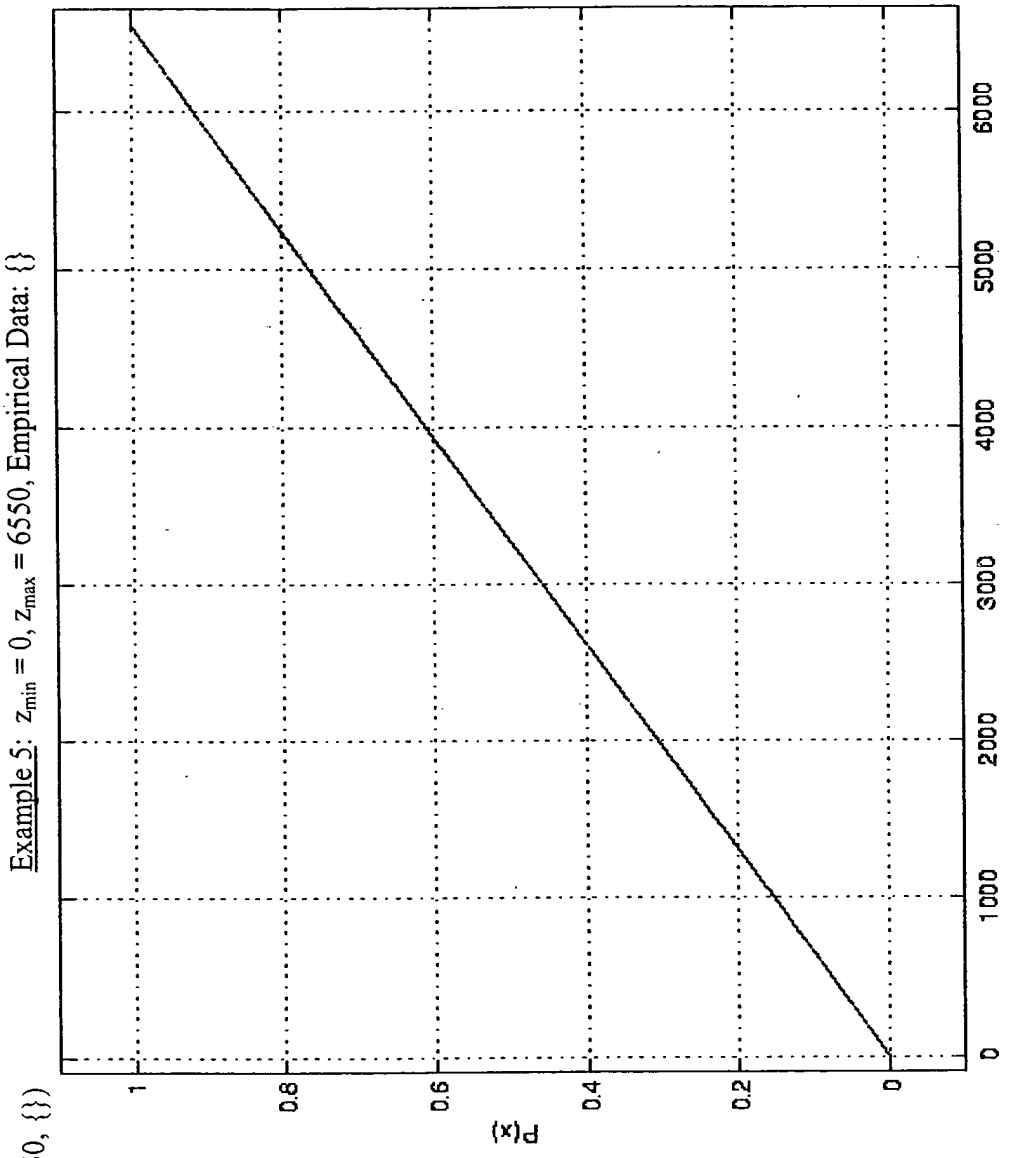
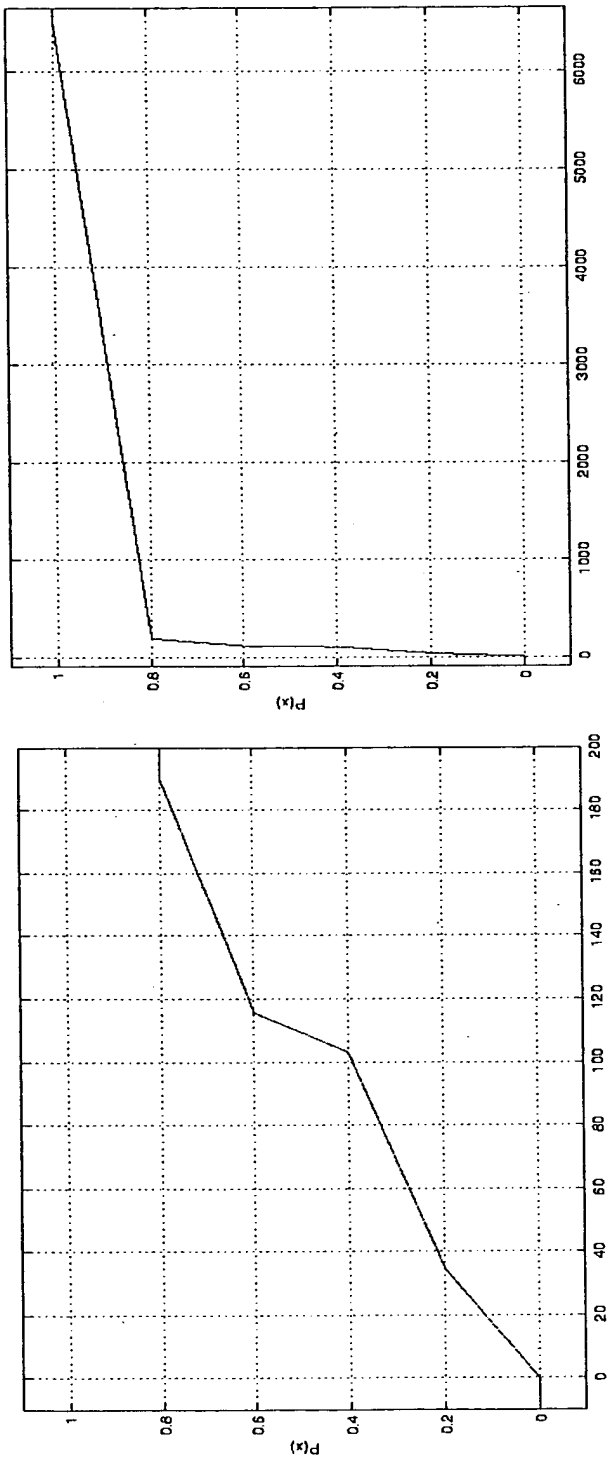


FIG. 32
Graph of $P(x; 0, 6550, \{\})$

FIG. 33



Graph of $P(x; 0, 6550, \{34.7, 103.1, 115.6, 189.9\})$

Example 6: $z_{min} = 0$, $z_{max} = 6550$, Empirical Data: $\{34.7, 103.1, 115.6, 189.9\}$